



September 16, 2005

To Whom It May Concern:

In response to your request for comments on Gluten Free Labeling of Foods, I would like to provide the following information.

1. Currently we do not label any foods as gluten free. This is due to the fact that there are no test methods that can reliably test gluten to 0 ppm. Though we do not claim to be gluten free, our gluten statement does make reference to the Codex Alimentarius's proposed definition for a gluten free food. Their proposed definition for a gluten free food is one that has less than 20 ppm gluten.

We have researched the possibility of labeling our Wheat Free products gluten free. The only certifying agency we found that currently certifies gluten free is the Gluten Free Certification Organization (<http://www.gfco.org/>). As quoted from an informational e-mail, "GFCO Standards are based on research and review of other country's regulations. The standard GFCO uses is 10 ppm gluten (Gliadin)".

2. Our Wheat Free products are made from ingredients that do not contain gluten.
3. We use soy flour in our Organic Wheat Free Tamari Soy Sauces. These facilities use dedicated and do not contain wheat, barley, or other gluten containing grains.
4. We process our Wheat Free products on the same production lines, using the same production equipment. To prevent contamination we thoroughly clean and sanitize our processing lines and equipment prior to running wheat-free product. We also have a detailed purge and cleaning recording log to monitor this.
5. The final product is tested for gliadin using a quick test.
The cost per test is around \$10.00.
6. There are three companies which make a qualitative gluten test kit, all of which employ the immunochromatographic principle for detection. They are Elisa Technologies Company, R-Biopharm and Nippon Ham Company (Japan). The Elisa Technologies Co. can only detect gluten. R-Biopharm's can detect only gliadin.

Nippon Ham's kit can detect all protein derived from wheat, which includes glutenin, gliadin, albumin, and α -amylase inhibitor. The antigen used in the Nippon Ham qualitative kit is that same as that of their quantitative kit, making it very reliable. Unfortunately the Nippon Ham kit as well as the others can not detect denatured wheat protein.

However, recently, Nippon Ham succeeded in making an improvement to the Elisa kit. Their improved kit is able to detect denatured protein in food. Last year Nippon Ham held a conference and received positive feedback from Elisa Technologies Co and R-Biopharm, regarding this new kit. Nippon Ham plans to sell this new kit in the near future.

The quick test we currently use to evaluate our product is done using the r-biopharm RIDA Quick Gliadin test kit. It is intended to detect gliadin in gluten-free food and beverages.

- a. This test kit uses "immunochromatographic principles and employs the monoclonal r5-antibody which is specific for the detection of gliadin from wheat and prolamins from rye and barley in food.
- b. The test is sensitive to 5 ppm
- c. The test kit is qualitative
- d. Our test kit can not detect denature wheat protein. Our fermentation process and pasteurization denatures the wheat and soy protein that are found in our soy sauces. Though our only products of concern, for gluten, are our Wheat Free products, we are unable to guarantee 100% gluten free due to the fact that our test kit is unable to qualitatively determine if denature wheat protein is present. If cross-contamination issues were present, we may not be able to detect it. Also, it is still unsure how denatured wheat affects allergy symptoms. It is not sure whether or not amino acids or amino acid chains, from denatured wheat, affect persons having a wheat allergen.
- e. The cost of the test is approximately \$10 per sample.

Other Information:

Attached is a study titled "Degradation of wheat allergen in Japanese soy sauce". This study shows that the wheat protein is not present after the fermentation process. In this study, researchers used the serum from serious allergen patients. It is known that the elements which cause the allergen are gluten and α -amylase inhibitor.

Please let me know if you have any questions. Thank you for allowing us the chance to provide information and our opinions for the Gluten-Free label claim.

Sincerely,

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Quality Control

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